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[REDACTED] EXAMINER

STARSIAK, JOHN S

ART UNIT	PAPER NUMBER
1753	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)	
9/526,920	<i>David Le Febre</i>	
Examiner	Group Art Unit	
<i>J. STARSIAK</i>	1753	

**—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

Responsive to communication(s) filed on 16 March 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1 - 62 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1 - 62 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

### Application Papers

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

All  Some\*  None of the:

Certified copies of the priority documents have been received.

Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

Copies of the certified copies of the priority documents have been received

in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, 5, 8

Interiview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other \_\_\_\_\_

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## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the embodiment wherein the continuously varying resistor comprises a filament recited in claims 5 and 31; the embodiment wherein the continuously varying resistor comprises a packing recited in claims 6 and 32; the embodiment wherein the continuously varying resistor has a material property that varies as a continuous function of position of position along said longitudinal axis, the first orientation electric field generator recited in claims 16,17,42,43; the second orientation electric field generator recited in claim 19; the analyte concentrator recited in claims 22, 51( the analyte concentrator is illustrated by a “black box”, however it does not appear to be “off-the-shelf” technology as is required if “black box” illustration is used for an element) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59 and 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The application as originally filed does not support the use of a pump to balance the force produced by the continuous electric intensity gradient generator.

Claims 1-62 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification is replete with defects such as terms which are nor clear, concise, and exact too numerous for the examiner to point out in detail. The following defects are REPRESENTATIVE of the more serious defects. For example the applicant states that using contour electrodes to define a portion of the separation channel results in a continuous electric field intensity gradient. For example, the specification recites page 30, lines 15 and 16, "The shape of the contour of the resistors causes the channel voltage gradient to vary in a *predictable*

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*manner.*" The applicant fails to provide any guidelines, e.g. design equations, design the contour electrodes to produce a desired voltage gradient. The examiner did a search of USPAT, EPOABS, JPOABS, DERWENT, and CAPLUS, and could find no teaching of the use of contour resistors to create a continuous electric field intensity gradient. Moreover, the examiner could not find even one occurrence of the term "contour resistor". The applicant presents no experimental evidence or theoretical reasoning that contour resistors will produce a continuous electric field intensity gradient. Similarly, the applicant broadly recites continuously varying resistors comprising one of the following: 1) a filament within the first separation channel, 2) a packing within the first separation that varies in resistivity as a continuous function of position along the longitudinal axis, 3) a conductive material having a cross section shape which varies as a continuous function of position along the longitudinal axis, 4) a contour resistor has a material property that varies as a continuous function of position along said longitudinal axis. The written description of the invention provides no design or fabrication details of any of these resistors and none of these resistors is illustrated. The written description discloses four electrical systems: 1) a continuous electric field intensity generator, 2) an electroosmotic flow generator, 3) a first orientation electric field generator (optional), 4) a second field orientation electric field generator(optional). The disclosure of the last two is inadequate for the following reasons. The structure of the first orientation field generator is the same as one possible structure for the electroosmotic generator. This raises the question, i.e. how is the first orientation electric field generator different from the electroosmotic flow generator? The second orientation electric field

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generator is only described in terms of desired results. In addition, the limited disclosures of the first orientation electric field generator and the second orientation electric field generator are in isolation, i.e. no disclosure of structural relationships to other elements. Hence, there is no disclosure of embodiments comprising the combination of a continuous electric field intensity generator, an electroosmotic flow generator, and a first orientation electric field generator or the combination of a continuous electric field intensity generator, an electroosmotic flow generator, a first electric field orientation generator, and a second electric field generator. The function of the electroosmotic generator is unclear. Page 6 of the specification recites, “an electroosmotic flow generator configured *to generate an electroosmotic flow...*”. Page 8 of the specification, “The electroosmotic flow generator can comprise a first plate disposed adjacent one side of the containment and configured *to alter the zeta potential* on an interior surface of the separation channel adjacent the first side of the containment, and a second plate adjacent a second side of the containment configured *to alter the zeta potential* on the interior surface of the containment [separation channel] adjacent the second side of the containment. How can the same element of the invention have two different functions. The latter function is consistent with the prior art. However, if the latter function is correct then calling this element an electroosmotic flow generator is repugnant to the normal meaning of “generator”. On page 23 the specification recites, “two lateral field electrodes” and “contour electrodes”. From fig. 8 it looks like “contour electrode 74,76 ” are the same element as contour resistors. What are these elements? resistors or electrodes? What term(s) in the claims if any correspond to the “lateral field electrodes? There is

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some description of the analyte concentrator. However, the analyte concentrator is illustrated only as a black box. Such illustration is permitted only if the analyte concentrator is an “off-the-shelf” device. See *Ex parte Sziklai*, 110 USPQ 325.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, “an electroosmotic flow generator configured to generate an electroosmotic flow along the longitudinal axis of the first separation channel...”. This recitation is indefinite for two reasons. First, the function recited of the “electroosmotic flow generator” recited in the description of the invention. Specifically, page 10, line 22-page 11, line 5, recite, ”The electroosmotic flow generator can comprise a first plate disposed adjacent one side of the containment and be configured *to alter the zeta potential on an interior surface of the separation channel*, and a second plate adjacent a second side of the containment configured *to alter the zeta potential on an interior surface of the containment [ separation channel] adjacent the second side of the containment*.”. The recitation in the description of the invention is consistent with the prior art. Second, if the function of the “electroosmotic flow generator” in the written description of the invention is the correct one, then calling this element(s) an “electroosmotic flow generator” is repugnant to the normal definition of the term “generator”

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(i.e., one that generates, causes or produces). In other words, the two plates recited in the written description of the invention in the written description of the invention do not generate an electroosmotic flow. For example electrodes at both ends of the separation channel are required. Claim 2 recites, “wherein the electroosmotic flow generator comprises a power supply and a distributed source of potential...”. This recitation is indefinite for two reasons. First the written description of the invention recites “distributed resistors” but not “distributed sources of potential”. MPEP 608.01 (o) states: “The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure to its import; and in mechanical cases, it should be identified in the descriptive portion of the specification by reference to the drawing, designating the part or parts therein to which the term applies.”. Second, it would appear that the power supply constitutes the “source of potential”. Claim 3 recites, “wherein the continuous electric field intensity gradient generator *further* comprises...”. Since no structure for the “continuous electric field intensity gradient generator” is recited in claim 1 (i.e., just function is recited) the phrase “further comprising” should be changed to comprising. Claim 4 recites, “A system as in claim 3 wherein the continuous electric field intensity gradient generator comprises a continuous varying resistor”. This recitation is a double recitation because claim 3 recites, “wherein the continuous electric field intensity gradient generator further comprises... a continuously varying resistor.” Similarly, the clause in claim 4 which begins, “whereby an electrical potential ...” is a double recitation. Claim 5 recites, “A system as in *claim 4*, wherein the continuously varying resistor comprises a filament within the

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first separation channel.”. This recitation conflicts with a recitation in claim 4, i.e., “a continuously varying resistor comprising a contour resistor...”. Claim 6 recites, “A system as in claim 4, wherein the continuously varying resistor comprises a packing...”. This recitation conflicts with a recitation in claim 4, i.e., “ a continuously varying resistor comprising a contour resistor...”. Claims 7 and 8 recite, “A system as in claim 3, wherein said contour resistor...”. Both of these recitations lack proper antecedent basis , i.e. a contour resistor is not recited in claim 3. Claim 15 is indefinite because its recites a different function from that recited for the “electroosmotic flow generator” recited in claim 1 , upon which claim 15 depends. Claim 16 recites, “A system as in claim 1, further comprising a first orientation electric generator”. This is recitation is indefinite for two reasons. First, this recitation fails to recite any structural relationships between the “first orientation electric field generator” and any of the elements recited in claim 1. Second, the written description of the invention, while containing some discussion of a “first orientation electric field generator” the written description fails to describe a device consisting of a continuous electric first intensity gradient generator, an electroosmotic flow generator, and a first orientation electric field generator. Claim 17 recites, “..wherein the first orientation field generator comprises an electroosmotic flow generator...” What follows this recitation is essentially identical to claim 15. This claim raises the following questions. One, are the first orientation electric field generator and electroosmotic flow generator the same element?. Two, if they are not what is the difference? Three, can “one generator” be both the “first orientation generator” and the “electroosmotic flow generator”? Claims 21, 47, and 53 recite,

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“said second separation channel further comprising a second electric field generator...”. These recitations are indefinite for two reasons. One, reciting that a channel can comprise a “electric field generator” is repugnant to the normal meaning of a channel. Second it is unclear what is meant by a second electric field generator when “a first electric field generator” is not recited in the proceeding language of the claims. Claim 26 and 52 are indefinite because they recite a second electric field generator without reciting a first electric field generator in the proceeding language of the claim. Claims 18, 27, and 44 are indefinite because it doesn’t recite an structure. Claim 28 recites, “A system as in claim 26, wherein the electroosmotic flow generator...”. This recitation does not have proper antecedent basis in claim 26. Similarly, “the electroosmotic flow generator” recited in claim 41 does not have proper antecedent basis. Claims 43 and 44 are rejected for the same reasons as claims 16 and 17, respectively. Claim 45 recites, “further comprising a second orientation electric field generator...”. This recitation is indefinite for several reasons. One the claim fails to recite and structural relationships between the “second orientation electric field generator” and the other elements recited in the claim. Two, while there is some limited discussion of “a second orientation field generator” in the written description of the invention there is no description of a device with all the elements recited in this claim in the written description of the invention. Claims 50 and 56, recite, “further comprising a first electrode...and a second electrode...”. From the written description of the invention it is unclear whether these electrodes are actually additional electrodes or a further limitation on elements already recited,

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e.g., “analyte concentrator, second electric field generator”. The remaining claims are rejected because they depend on at least one of the above claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for a patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,9,10, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Ivory et al.

Ivory et al teaches [col. 5, lines 9-19]: “The present invention provides an electrophoretic device and method in which a charged solute such as a protein can be simultaneously separated and concentrated by applying a constant force (e.g., hydrodynamic force due to buffer flow) and opposed by a gradient in a second force (e.g. electric field). According to the invention, a constant hydrodynamic force is opposed by a gradient in the electric field which allows charge molecules to

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focus in order of their apparent electrophoretic mobilities.”. Ivory et al teaches [col. 5, lines 50-54]: “The device can optionally include, in addition to the electrode array, an electrode pair. In this embodiment, the electrode’s of the pair are positioned adjacent opposing ends of the electrode array.”. Ivory et al. Teaches [col. 6, lines 54-60]: “As noted above, liquid flow through the separation chamber opposes the direction of electrophoretic migration of the solute and can be driven by any one of a variety of forces including electric field, pressure, vacuum, or other motive force. Ivory et al. teaches [col. 17, lines 33-35]: “Electroosmotic flow (EOF) is generated by charges present at the inner surface of the column or at the surface or interior of packing beads.”. Ivory et al. teaches [col.18, lines 41-43]: “An electric field gradient in any shape, linear or nonlinear, continuous or stepwise, can be produced with a limitation to the conductivity of the buffer.”. Regarding claim 11 see Table 4 of Ivory et al. Although claim 1 recites, “said first separation channel configured to contain an electrolyte solution within the interior channel volume, said separation channel providing the only flowpath for both the analyte sample and the electrolyte solution, claim 1 reads on Ivory et al for the following reasons. First, the separation channel can read on the focusing chamber 10 of Ivory et al. Second, the latter portion of the above recitation is non-structural and should not be given weight. It is well-established that in *apparatus claims* the claims must distinguish over the prior art by structural recitations.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (703) 308-1791. The examiner can normally be reached on Monday to Friday from 8:00 AM to 3:30 PM and on Thursday and Friday from 8:00 AM to 12:00 PM .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tam Nguyen, can be reached on (703) 305-7715. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



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John S. Starsiak Jr.

05 March 2003